Pharmacist or pharmacy team

A technical reading route through U.S. compounding pathways, bulk ingredient eligibility, supplier provenance and analytical reports. It explains the questions behind 503A and 503B rather than treating a supplier certificate as authorization. Official sources support further review.



Elias / fictional visitor

YOUR LEARNING JOURNEY

Create a product-identity comparison that makes differences visible without treating every preparation as interchangeable. Keep unresolved differences visible in the comparison.

Start with the applicable framework, trace the ingredient documentation, then examine what the analytical report establishes.

Compounding can address particular patient needs, but compounded medicines do not receive FDA premarket approval. Registration, listing and an NDC do not establish approval or interchangeability.

Open the current online guide

Sources and related guides remain accessible on the website. All role paths are open to every reader.

Portrait: fictional illustration, not a real patient, professional reviewer or endorsement. This handbook provides education, not individual medical or legal advice.

Contents

Read in order for a foundation, or use the linked contents to find a specific topic. Page numbers refer to this edition.

SUGGESTED START

1. 503A and 503B: understand the pathway before the product
2. API provenance: trace the ingredient, not just the logo
3. Read a certificate of analysis without filling in the blanks

Continue with the reading path and books, then record your findings in the learning worksheet.

Know which product the evidence describes / 3

503A and 503B: understand the pathway before the product / 4

API provenance: trace the ingredient, not just the logo / 6

Testing the material: seven different questions / 7

Read a certificate of analysis without filling in the blanks / 9

What “gray market” leaves unexplained / 10

Crossing a border: separate quality, approval and admissibility / 12

Where to report a problem and how to check a pharmacy / 13

Reading path and books / 14

Examples in practice / 15

Questions and explanations / 16

Glossary / 18

Learning worksheet / 19

Know which product the evidence describes

A molecule name is a starting point, not a complete product description. Record the active ingredient, chemical form, formulation, route, manufacturer or compounder and the document date. Products using similar names may differ in ways that matter. A result for one preparation does not automatically establish the performance of another.

FDA approval concerns a particular drug product and its authorized labeling. A facility registration, product listing or National Drug Code does not mean FDA has approved the product. A company can have legitimate paperwork for one activity without every product or claim being authorized.

Compounded drugs are prepared under a different framework and are not FDA-approved. They can serve particular patient needs, but FDA does not review each compounded product for safety, effectiveness and quality before marketing in the way it reviews approved medicines. The 503A and 503B pathways have different conditions, explained below.

Investigational means a product or use is being studied; it does not mean success is established. Research-use labeling concerns a claimed purpose and cannot establish suitability for human use. Keep regulatory status, analytical quality and clinical evidence as three separate entries. None can substitute for the other two.

Build a simple comparison: what the paper studied, what the official label describes, and what the current document or service names. Mark missing information rather than filling it with a brand assumption. This comparison is useful for a patient preparing questions and for a professional reviewing a brochure.

Worked learning example

Two documents use the same ingredient name. One describes an approved finished medicine; the other describes bulk powder with a laboratory report. The shared name does not make the powder an approved medicine. Ask what each document actually establishes before carrying claims between them.

READ THE SOURCE

FDA - Is It Really FDA Approved?

FDA - Compounding and FDA: Questions and Answers

503A and 503B: understand the pathway before the product

Compounding means preparing a medicine for particular needs by combining, mixing or altering ingredients. In the United States, sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act establish different conditions for exemptions from certain federal requirements. They are not product-approval programs. A compounded medicine does not become FDA-approved because a pharmacy holds a license or an outsourcing facility appears in a registration database.

Section 503A concerns compounding by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician. Its prescription condition concerns an identified individual patient. Limited anticipatory compounding can occur under specified conditions before a prescription arrives, but that is not unrestricted authority to supply unassigned office stock. When all applicable conditions are met, the product can qualify for exemptions from premarket approval, adequate-directions labeling and federal current good manufacturing practice requirements. Other requirements still apply.

Section 503B concerns outsourcing facilities, where compounding occurs by or under the direct supervision of a licensed pharmacist. These facilities remain subject to current good manufacturing practice, often abbreviated CGMP. They may obtain individual prescriptions or supply healthcare providers with office stock: medicine held before a particular patient needs it. FDA conducts risk-based inspections, and reporting obligations apply. Registration is not a guarantee that every preparation, practice or transaction complies.

Bulk ingredients have separate eligibility gates. Under 503A, FDA describes an applicable USP/NF monograph route; when no applicable monograph exists, a component-of-an-approved-drug route; or, when neither applies, inclusion on the 503A bulks list. Under 503B, a substance generally needs inclusion on the clinical-need bulks list, or the resulting drug must be on the shortage list at compounding, distribution and dispensing. A monograph is a published quality standard, not approval of every preparation made from the ingredient.

A valid certificate of analysis and manufacture by an FDA-registered establishment are additional bulk-substance conditions, not substitutes for eligibility. Interim enforcement policies are also distinct from the statutory lists: nomination or Category 1 status is not final list inclusion. Other limits, including restrictions involving essentially copies of available medicines, still need attention. Review the specific product, pathway and date rather than assuming that a familiar ingredient or a national shortage headline answers everything.

503A status as of October 31, 2026: interim Categories 1, 2 and 3 are not the final 503A bulks list. Category 1 concerns adequately supported nominations under evaluation; Category 2 identifies significant safety concerns; Category 3 concerns inadequate nomination support. Removal from Category 2 does not itself establish eligibility. An advisory-committee recommendation is nonbinding advice, not list inclusion. Addition to the final list requires FDA rulemaking; other 503A conditions still apply. Read the category record, committee record and final rule separately rather than treating one as a substitute for another.

Illustrative case: the clinic refrigerator

A clinic asks for unnamed-patient inventory. “Our supplier is a compounding pharmacy” does not resolve the office-stock question. The useful next questions concern the facility’s actual pathway, the exact preparation, the relevant federal conditions and applicable state rules. This example is a reading exercise, not clearance to obtain or administer stock.

Status-note sources checked October 31, 2026; this is not a claim that every retained source was re-reviewed.

READ THE SOURCE

FDA - Human Drug Compounding Laws

FDA - Provisions Applicable to Human Drug Compounding

FDA - 503A Bulk Drug Substances

FDA - 503B Bulk Drug Substances

FDA - Interim categories (PDF updated May 14, 2026)

FDA - July 23-24, 2026 PCAC meeting page

Federal Register - PCAC meeting notice, April 16, 2026

API provenance: trace the ingredient, not just the logo

An active pharmaceutical ingredient, or API, is the ingredient intended to provide a medicine’s pharmacological activity. An excipient serves another formulation role. A manufacturer makes material; a distributor moves it through commerce; a repackager transfers material into another container. One organization may perform several roles, but a reseller’s name does not identify the original manufacturing site. This distinction matters when interpreting records and investigating a quality problem.

FDA urges compounders to understand their API and excipient suppliers, the quality of the material and what testing has been performed. It also urges repackagers to identify the original API manufacturer clearly and maintain supply-chain transparency. The agency describes patient harm associated with component-quality problems. A useful document review therefore connects the chemical identity, original manufacturer, manufacturing site, intermediaries, batch identifiers and document dates instead of collecting unrelated certificates.

A certificate of analysis, or COA, reports specified test results for an identified sample or batch. Start by asking what was measured and how the report connects to the material. Identity, purity, content, microbial quality and other attributes answer different questions. A percentage without its method and meaning is easy to overinterpret. A purity result alone cannot establish sterility, clinical benefit, FDA approval or eligibility for a particular compounding use. Those are different conclusions requiring different evidence.

In its drug-manufacturing guidance, FDA discusses representative sampling, identity testing and establishing the reliability of supplier analyses. That context matters: a manufacturing quality system cannot be reduced to downloading a COA. Nor is every CGMP provision automatically a universal checklist for every research laboratory. The educational task is to recognize missing information and the applicable context, not to declare a batch released or independently certify a laboratory.

Keep three conclusions separate: what the organization says it does, what documents establish about this material, and what rules apply to the proposed use. Registration is not FDA approval. A sound provenance record can reveal unanswered questions without promising that a product is safe, legally eligible or appropriate for a patient.

Illustrative case: a report with no batch connection

A brochure displays a high-purity result but the report identifier cannot be linked to the item being discussed. The result may describe a tested sample; it does not establish that the item shares those results. Record the gap rather than filling it with an assumption about the entire supplier.

READ THE SOURCE

FDA - Know Your Bulks and Excipients Suppliers

FDA - CGMP Questions and Answers: Components, Containers and Closures

FDA - Is It Really FDA Approved?

Bachem - Vista Manufacturing Site

CordenPharma - API Manufacturing

Testing the material: seven different questions

An analytical laboratory studies the material submitted to it. Start with the question you want answered, then ask which method can answer it. A report about identity cannot silently stand in for a report about amount, contamination or clinical effectiveness. The sample, formulation, analytical method and acceptance criteria all shape what the result means.

Identity asks whether the material matches its stated identity. Laboratories may compare molecular mass, amino acid sequence, structural features or chromatographic behavior with a suitable reference. A matching mass alone does not establish every structural detail. Ask which features the method can distinguish, and whether additional methods are needed for the particular material.

Purity asks what else a method detected. A chromatographic purity percentage describes separated signals under specified conditions. It is not automatically the proportion of all powder that is peptide. Water, counterions, residual solvents and impurities outside the method’s detection capability can require separate measurements. Two methods may produce different descriptions because they observe different properties.

Content, sometimes called assay or strength, asks how much target substance was measured. Read the units and calculation basis: mass per container, concentration or percentage of a stated claim. Biological potency asks a different question: whether the material produces specified biological activity in an appropriate assay. Chemical content alone does not establish biological activity, and an activity assay does not establish effectiveness in patients.

Sterility testing looks for viable microorganisms using a defined method and sample plan. A reported result concerns the material and conditions tested; it is not a universal guarantee covering every container or every contamination risk. Bacterial endotoxin testing is separate. Read its method, units, limit and sample-suitability information. Endotoxin testing does not cover every pyrogen. USP includes both Chapter 85 and Chapter 86 approaches; the latter uses recombinant reagents.

Stability asks whether specified qualities are maintained over time under defined conditions. A fresh COA is a snapshot, not a shelf-life study. Expiry support depends on the formulation, packaging and storage conditions studied. A reference standard is characterized material used for comparison. Traceability is a documented measurement chain to a reference, not a blanket endorsement of a laboratory or supplier. Measurement uncertainty describes uncertainty associated with a result; it should not be confused with permission to ignore a failed criterion.

One result cannot answer every question

A fictional sample has high chromatographic purity but no content, sterility or endotoxin results. The supported statement is that the submitted sample met the stated chromatographic criterion. Its amount and those microbiological properties remain unassessed. Nothing in that limited result establishes clinical benefit or suitability for human use.

READ THE SOURCE

USP authors: Reference Standards to Support Quality of Synthetic Peptide Therapeutics

FDA: Pyrogen and Endotoxins Testing-Questions and Answers, March 2026

USP Chapter 1085: Guidelines for Bacterial Endotoxins Testing

FDA: Expiration Dates-Questions and Answers

NIST: Metrological Traceability

Read a certificate of analysis without filling in the blanks

A certificate of analysis, or COA, records analytical findings for an identified material or sample. It is useful evidence only when its scope is understood. It is not interchangeable with a manufacturing history, clinical study, regulatory approval or guarantee about every item bearing a similar label. Begin with the identifiers rather than the biggest percentage on the page.

Match the laboratory name, report number, sample identifier and stated lot or batch. Check receipt, testing and issue dates, and whether the report was revised. Establish who selected and submitted the sample and what material the laboratory actually received. A report cannot establish the history of material it never handled. A seller’s screenshot may omit pages, qualifications or revisions; report authenticity can be checked through independently located contact details for the issuing laboratory.

For each result, read four things together: the property measured, the method, the units and the acceptance criterion. A specification describes tests and criteria used to judge the material. A pass means the reported finding met that stated criterion; it does not make unmeasured properties pass too. The appropriateness of the criterion is a separate question. If the report does not explain its basis, ask what standard or specification was used.

Read purity and content separately. Chromatographic peak-area purity describes signals separated by a particular analytical method. A content assay measures an amount using its own method and calculation basis. A product can have a high chromatographic percentage while containing less target substance than its stated claim. Water, counterions and other components are reasons that the mass of powder and the mass of target peptide are not necessarily identical.

Not tested means no result for that question; it is neither a pass nor a demonstrated failure. Not detected means the method did not detect the substance under its conditions and detection capability; it does not necessarily mean zero. A result below a quantification limit cannot automatically be treated as a precise amount. When relevant, ask about method suitability, the reference standard and measurement uncertainty rather than comparing bare numbers across unlike methods.

Keep the conclusion as narrow as the evidence. A chemical report without microbiological testing cannot establish sterility or endotoxin status. A single test date does not establish shelf life. A certificate for one submitted sample also does not show that a treatment works in humans. The practical reading question is: which test, on which sample, against which criterion, and what remains unknown?

Invented COA exercise: high purity, failed amount

This is an invented learning example, not a real product or report. Teaching Material A, lot EDU-001: identity is consistent with the stated sequence under the named method. HPLC purity is 99.2% area against an invented criterion of at least 98.0%, so that criterion passes. Content is 8.1 mg per container against a nominal 10.0 mg claim and an invented acceptance range of 9.0-11.0 mg, so content fails: 8.1 divided by 10.0 equals 81% of the claim. Biological potency, sterility and endotoxin were not tested; no stability study was supplied. Those questions remain unanswered. All limits here are fictional educational values, not product standards or use instructions.

READ THE SOURCE

USP authors: Peptide reference standards, purity and content

NIST: Reference materials and certified values

NIST: Traceability and uncertainty

FDA: Expiration Dates-Questions and Answers

What “gray market” leaves unexplained

“Gray market” is a loose conversational label, not a quality grade or a legal conclusion. It can blur several different issues: an unapproved product promoted for human use, an authentic product outside a documented supply chain, a counterfeit identity, misleading research labeling, or a preparation that does not meet a compounding pathway’s conditions. Name the actual question before deciding what a document or testimonial proves.

A research-use statement describes a claimed purpose; it does not automatically settle intended use. In a March 31, 2026 warning letter to Gram Peptides, FDA explained that website evidence established intended human use despite research-only and not-for-human-consumption disclaimers. This is an example of FDA’s stated enforcement findings, not a final court judgment or a claim about the company’s later status. The broader lesson is to read the surrounding claims and presentation, not a disclaimer in isolation.

Counterfeit and unapproved are also different concepts. Counterfeit identity concerns a product falsely represented as authentic. Unapproved status concerns the absence of applicable approval. Lawfully compounded medicines are themselves not FDA-approved, so “unapproved” alone does not describe every applicable legal condition. Conversely, calling something compounded does not establish that it meets those conditions. Classification requires the exact product, source, claims and regulatory context.

Chemical names require precision. On its current GLP-1 concerns page, FDA states that retatrutide and cagrilintide cannot be used in compounding under federal law. The same page distinguishes semaglutide sodium and acetate from the active ingredient in approved medicines and says the agency is unaware of a lawful basis for their compounding use. These are product-specific statements, reviewed October 31, 2026; do not generalize them to every peptide, salt or jurisdiction.

A separate FDA clarification dated April 1, 2026 discusses restrictions on preparations that are essentially copies of commercially available drugs. It explains that adding another active ingredient does not automatically avoid those restrictions. That dated statement should remain dated: it is not an independently checked live shortage-database result. An April 30, 2026 announcement proposing exclusion of three GLP-1 substances from the 503B bulks list was a proposal, not a final decision.

For an educational review, record exactly what is known: the named item, original source, date, claimed use and unresolved identity or quality questions. Distinguish a reported adverse event from proven causation and a compelling anecdote from a controlled study. Neither a disclaimer nor a dramatic personal story turns an uncertain product into a verified clinical option.

Illustrative case: “research only” beside human promises

A page says research only while its surrounding language promises personal recovery or weight loss. A reader should record the tension between those messages and examine the applicable rules. The footer alone cannot answer whether the product is being marketed for human use.

READ THE SOURCE

FDA - Gram Peptides Warning Letter, March 31, 2026

FDA - Concerns with Unapproved GLP-1 Drugs

FDA - Compounding Questions and Answers

FDA - Compounding Clarification, April 1, 2026

FDA - Proposed 503B Exclusions, April 30, 2026

Crossing a border: separate quality, approval and admissibility

Import admissibility asks whether a product can enter a jurisdiction under the applicable rules. It is not the same question as whether a laboratory result looks convincing or whether another country has approved a medicine. An API can itself fall within the legal definition of a drug. Understanding the intended use therefore matters before treating a shipment as a simple purchase of laboratory material.

FDA explains that human-drug import review can involve registration, listing, drug applications, labeling and current good manufacturing practice requirements, as applicable. Entry information includes the manufacturer, importer or consignee, product description and intended use. FDA can seek more information, examine or sample products, or detain them. A foreign supplier’s assurances do not replace the relevant product and transaction review, and registration should not be mistaken for approval.

FDA Import Alert 66-80 addresses quality concerns involving GLP-1 receptor agonist APIs. Its detention-without-physical-examination framework excepts the products and firms identified on its Green List, based on evidence of apparent CGMP compliance. Do not substitute a supplier’s general assurance of compliance for checking the actual firm and product listing. This is a GLP-1 API alert, not a rule covering every peptide, and a Green List entry does not establish product approval or resolve all other import conditions. As of October 31, 2026, read the live alert alongside FDA’s GLP-1 concerns page.

Personal importation is a separate, limited context. FDA defines it as a product not intended for further sale or distribution into U.S. commerce. The agency describes circumstances in which personnel may exercise discretion, but that is not a general exemption or guaranteed admission. A plan to resell or distribute material is not transformed into personal importation by calling the order small or describing the purchaser as an individual. Foreign approval does not establish U.S. approval.

Exports require their own analysis. FDA identifies provisions governing commercial and investigational human-drug exports, and distinguishes these from personal-use exports. Some unapproved drugs may qualify for export under statutory conditions, including relevant destination-country requirements. Such pathways are conditional, not blanket permission to export any substance. A document associated with export does not establish U.S. marketing approval or erase the destination’s rules.

Keep a jurisdiction record with the origin, destination, exact product identity, intended purpose, parties involved and date of review. Add the official source that addresses each question and mark unresolved points. For educational purposes, this is more useful than a single “legal/illegal” checkbox: quality evidence, manufacturer identity, applicable authorization and border rules can each be incomplete in different ways.

These records explain different questions: quality, product status and border admissibility. A document addressing one question cannot settle all three.

Illustrative case: foreign approval plus a certificate

A business holds evidence of approval abroad and a laboratory report. Those documents may answer particular questions, but neither establishes that the proposed U.S. import, resale or compounding use meets its conditions. Record which issue each document addresses and which issues remain open.

Import Alert 66-80 addition checked October 31, 2026.

READ THE SOURCE

FDA - Importing Human Drugs

FDA - Personal Importation

FDA - Export Requirements for Human Drugs

FDA - Export Requirements for Unapproved Drugs

FDA - Import Alert 66-80 and Green List

FDA - Concerns with unapproved GLP-1 drugs

Where to report a problem and how to check a pharmacy

FDA MedWatch accepts reports of adverse events and product-quality problems. Record the product name, manufacturer or compounder, lot if available, dates, what happened and relevant packaging or photographs; distinguish what you observed from what you suspect caused it. A report communicates a concern and does not itself prove causation.

Use FDA BeSafeRx to learn how to evaluate an online pharmacy, then follow FDA’s state-pharmacy directory to the relevant board’s license lookup. Match the legal name and address, check the current license record and contact the board when an entry is unclear. A license lookup and a product-approval record answer different questions.

Worked learning example - fictional

A package names a dispensing pharmacy different from the website brand. Look up the pharmacy’s legal name and address, not just the platform name. If reporting a damaged container, retain its lot number and describe the damage without assuming which organization caused it.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FDA - Reporting serious problems

FDA - BeSafeRx

FDA - State pharmacy license lookup directory

Reading path and books

1. Identify the approved reference

Start with the exact medicine and indication rather than an ingredient-level generalization.

2. Review verification categories

Keep pharmacy identity, product provenance and compounding classification separate.

3. Read the applicable evidence

Trace the formulation and population used in research before carrying its findings to another preparation.

Continue in the Church Library

Choose the level that fits your background. Book links lead to the Library, where reading options and any affiliate disclosures are shown.

Testing Treatments - Evans, Thornton, Chalmers and Glasziou

Start with fair comparisons and uncertainty. The library entry includes an official free reading option. Published in 2011; use current official sources for regulatory questions.

The Art of Statistics - David Spiegelhalter

Go deeper into denominators, uncertainty and interpreting data. Read alongside the actual study rather than using a statistical slogan as a verdict.

Bottle of Lies - Katherine Eban

Investigative cases provide context for manufacturing oversight and documentation. The book is not a current supplier assessment or a conclusion about every generic medicine.

Browse all Library rooms

Examples in practice

These examples identify published resources and their uses; they are not evaluated services.

Intertek - peptide characterization

Analytical example: provider-published descriptions of identity, impurity analysis, stability and biological activity assays. Read to compare the questions different methods answer; this is not an endorsement or independent accreditation verification.

Eurofins - peptide characterization and development

Analytical example: describes complementary separation, structural, impurity and stability methods. Published capabilities do not guarantee acceptance of a particular sample or suitability for a particular project.

Bachem - Vista peptide API manufacturing

Company-described example of clinical-to-commercial peptide API manufacturing in Vista, California. The page lists GMP and non-GMP capabilities, illustrating why a company name alone does not establish a specific item’s grade. Reviewed October 31, 2026; not an endorsement, current inspection assessment, purchase direction or finding of compounding eligibility.

CordenPharma - API manufacturing and peptide services

Company-described example of peptide API development, cGMP manufacturing, analytical services and clinical/commercial supply. Reviewed October 31, 2026. This illustrates an industry role; it does not establish availability, approval, suitability or legal eligibility of a particular product or transaction.

Questions and explanations

Which named product and formulation does the approval describe?

Use the current official record for the named finished medicine and compare its active ingredient, dosage form, route and labeling with the preparation under discussion. Approval of that product does not transfer to every compounded or bulk presentation with the same ingredient name. For example, a branded injection’s approval record cannot serve as the approval record for a separately compounded preparation. Preserve the exact distinction when counseling or reviewing written material.

Read the source: it really fda approved

Read the source: compounding and fda questions and answers

What is documented, and which details still need confirmation?

Separate confirmed product identity, provenance, regulatory category and analytical findings from missing or secondhand information. A complete-looking packet may still leave the original manufacturing site or batch connection unresolved. For example, an invoice identifies the distributor and a COA identifies a sample, but neither alone proves that the sample represents the dispensed preparation. List the unanswered question and the document or responsible organization needed to resolve it.

Does the evidence concern the same product, route and population?

Match the preparation, route, population and outcome rather than stopping at the molecule name. Differences in these features can limit how directly the finding applies. For example, a human study of one injected formulation does not establish the absorption or clinical effect of a different oral preparation. Describe the available evidence and the untested extrapolation separately, without implying interchangeability.

Who originally manufactured this material, and how does this report connect to this batch?

Trace the API record back to the original manufacturer and site through each relevant distributor or repackager, and match the lot identifiers with the analytical record. FDA’s supplier guidance emphasizes transparency about the original API manufacturer and understanding supplier testing. For example, a repackager’s certificate should not be treated as identifying the original manufacturer when it names only the repackager. Record any missing link; a registered establishment and valid COA remain separate from eligibility for the intended compounding use.

Read the source: fda compounders know your bulks and excipients suppliers

Which attributes were not tested?

Build an attribute-by-attribute inventory of what the submitted report covers and what it omits. Distinguish an omitted test from a failed result, and distinguish analytical content from biological activity. For example, acceptable chromatographic purity and identity results do not answer an absent endotoxin assessment or establish shelf life. The appropriate conclusion concerns those reported attributes only, with further interpretation tied to the specific preparation and quality framework.

Glossary

Comparator
The reference group or intervention against which an outcome is compared, such as placebo or another treatment.

Endpoint
An outcome defined for a study. A biological measurement and a patient-important outcome are not necessarily the same thing.

Formulation
The composition and presentation of a product, including ingredients beyond the active substance.

Adverse event
An unwanted medical occurrence during observation; occurrence does not itself establish a causal connection to treatment.

Investigational
Under investigation. This describes research status, not proof of safety or benefit.

COA
Certificate of analysis: a report of specified tests and results for an identified material or sample. Its meaning depends on scope and provenance.

Identity
Whether a material matches the named substance within the methods and comparisons used.

Purity
A method-dependent assessment of detected components; chromatographic peak-area purity is not automatically total mass purity.

Assay / content
A measurement of the amount of a specified substance, stated with units and a defined basis.

Potency
Biological activity assessed by a specified assay; the term is sometimes used differently, so inspect the report’s definition.

Sterility
The absence of viable microorganisms; interpreting a sterility-test result requires its sampling and method context.

Endotoxin
A component of certain bacteria that can provoke inflammatory reactions. Endotoxin testing is distinct from sterility testing.

Traceability
A documented connection to an origin or reference. Measurement traceability and supply-chain provenance are related but different questions.

API
Active pharmaceutical ingredient: the substance intended to provide a medicine’s pharmacological activity. An API is not the same as a finished medicine.

503A / 503B
Different U.S. statutory pathways for qualifying compounded drugs. Neither makes a compounded drug FDA-approved.

CGMP
Current good manufacturing practice: requirements for manufacturing controls and quality. The applicable framework depends on the activity and product.

Gray market
An informal description of uncertain or unauthorized distribution channels, not a regulatory approval category.

Learning worksheet

Product identity comparison

Use these prompts to record what you understand, what remains uncertain and which source could answer the question.

Learning prompt	Filled-in fictional example
Product identity comparison	Fictional example: Identity ledger: source describes a finished injectable medicine; current document describes bulk material. Difference: product stage. Open question: which record addresses the actual preparation?

Record exact name, formulation, manufacturer or compounder and source document date.

Compare the studied product with the product being discussed; mark differences explicitly.

Record approval or compounding status and the relevant oversight category.

List unresolved identity, quality or evidence questions and who can answer them.

Educational information, not individualized medical or legal advice.

Explore another perspective in the Community Center